

KCC 4775 (K-C 17,129)
PATENT

infant" is not supported by the originally filed disclosure.

As stated in M.P.E.P. §2163.07, "[m]ere rephrasing of a passage does not constitute new matter. Accordingly, a rewording of a passage where the same meaning remains intact is permissible." Furthermore, the inclusion of a dictionary or art recognized definition known at the time of filing an application would not be considered new matter. Specifically, in the case of *In re Anderson*, 471 F.2d 1237 (CCPA 1973), the Examiner rejected a claim for containing language that had no antecedent basis in the specification and thus was new matter contrary to the requirements of 35 U.S.C. 132. In overruling the rejection, the Court of Customs and Patent Appeals, stated that "the question is not whether the word is used in the specification as filed but whether there is support in the specification for employment of the term in the claim."¹

Applicants assert that the instant case is such a case where Applicants have simply reworded a phrase that is consistently present in the original disclosure. Direct support for the claimed language "suitable for ingestion by a suckling infant" in claims 1, 17, 35, 53, 56, 58, and 65 can be found in original claim 65, and further, in no less than 23 passages of the originally filed application.² Specifically, original claim 65 was directed to a method of supplementing the nutrient intake of a breast feeding infant comprising transferring the omega-3 fatty acids from the nipple and breast of the woman to the infant during the breast feeding of the infant such that the omega-3

¹*In re Anderson* at 1244.

²See, e.g., Instant application as published (U.S. Application No. 2003/0105445) at the abstract, paragraphs 5-7, 13, 15-16, 30-32, 35-37, 39-41, and 45.

KCC 4775 (K-C 17,129)
PATENT

fatty acids are ingested by the infant. Furthermore, throughout the specification, Applicants note that the composition can be ingested by an infant during breast feeding and lead to improved health for the child.³

As defined in Webster's on-line dictionary, the term "suitable" means "appropriate for a condition or occasion; proper; right."⁴ Applicants note that the instant specification discloses that "it is important that any additives introduced onto the breast pad in combination with the [omega-3 fatty acids] not be harmful to a baby if ingested by the baby during breast feeding."⁵ As such, Applicants' instant invention requires that the composition be appropriate or meant for ingestion by the suckling infant.

Additionally, at paragraph 15 of the originally filed application, it is stated that "...fatty acids can be introduced onto the breast pad in a *suitable* composition to improve the skin health of the mother and the health of the suckling baby." (Emphasis added). To be a suitable composition for improving the health of the suckling baby, the composition, by definition, must be suitable or appropriate for ingestion by the baby, otherwise it cannot improve the health of the baby. As such, the

³See, e.g., Instant specification on page 13, lines 25-28 and page 15, lines 29-32.

⁴Website available at www.webster-dictionary.org/definition/suitable. In a second definition, suitable means "meant or adapted for an occasion or use." Similar definitions can be found on www.TheFreeDictionary.com/suitable and www.hyperdictionary.com/dictionary/suitable. Applicants are submitting these references with this Letter To Patent And Trademark Office.

⁵ Instant specification on page 17, lines 13-15.

KCC 4775 (K-C 17,129)
PATENT

composition is suitable for ingestion.

It is noted that the Office claims that "all compositions are suitable for ingestion." However, the dictionary definition of "suitable" indicates that this is not the case; all compositions are not appropriate, proper, or right for ingestion. Specifically, the compounds of Allen are not proper or right for ingestion as they could kill the baby.

Based on the foregoing, Applicants assert that the claimed language "suitable for ingestion by a suckling infant" is clearly and plainly supported by the instant specification. As such, Applicants respectfully request reconsideration of the objection to the specification, and allowance of all pending claims.

1. Rejection of Claims 1-71 Under 35 U.S.C. §103(a)

Reconsideration is requested of the rejection of claims 1-71 under 35 U.S.C. §103(a) as being unpatentable over Buckley et al. (U.S. 5,281,186) and further in view of Allen (U.S. 6,361,806).

Claim 1 is directed to a breast pad for absorbing fluid leaking from the breast of a woman and minimizing the soiling of clothing worn by the woman. The breast pad has a front side which faces the breast and a back side which faces the clothing. The front side comprises from about 0.1 g/m² to about 30 g/m² of a composition for improving breast and nipple skin health. The composition comprises omega-3 fatty acids. The composition is suitable for ingestion by a suckling infant.

The Office asserts that the claimed limitation "suitable for ingestion by a suckling infant" is not supported by the original disclosure. As noted above, support for the claimed limitation "suitable for ingestion by a suckling infant" can be found in the originally filed disclosure. Additionally, the Office notes that

KCC 4775 (K-C 17,129)
PATENT

even if the limitation, "suitable for ingestion by a suckling infant," can be read into the claim, it does not provide a structural difference between the instant claim 1 and the cited art. Specifically, the Office asserts that all compositions are suitable for ingestion; whether the composition may be safely ingested is a separate argument. Applicants respectfully disagree. As noted above, the dictionary definition of "suitable" is appropriate or proper for a condition or occasion. As such, a composition is suitable for ingestion only if it would be appropriate or proper for ingestion.

Buckley et al. disclose a protective breast cup arrangement comprising a plurality of breast cup members arranged to provide protection to an individual's breast region during sporting events. The cup arrangement may include a nipple pad formed from a lotion impregnated fluid absorbent sponge material. The lotion is of any type commercially available to afford protection and healing to an individual's skin or nipple.

Significantly, Buckley et al. fail to disclose a breast pad comprising from about 0.1 g/m² to about 30 g/m² of a composition for improving breast and nipple skin health comprising omega-3 fatty acids. Additionally, Buckley et al. fail to disclose a composition suitable for ingestion by a suckling infant. These are requirements of claim 1 and are important aspects of Applicants' invention. Recognizing that Buckley et al. fail to make such a disclosure, the Office cites Allen for combination with Buckley et al. in an attempt to find each and every element of Applicants' claim 1.

Allen discloses topical emollient compositions and methods that allow for topical administration of a balanced mixture of C₁₈ unsaturated fatty acids that is effective to penetrate

KCC 4775 (K-C 17,129)
PATENT

epithelial barriers and stimulate changes in fatty acid metabolism in subcutaneous adipose tissues. The compositions consist of hydrophilic:hydrophobic emulsions comprising a carrier, a vehicle, a compatible balanced fatty acid penetrant consisting of $C_{16:0}$, $C_{18:0}$ and $C_{18:1}$ fatty acid derivatives, a mixture of medicinal fatty acids, a natural anti-inflammatory compound, a natural analgesic compound, a natural estrogenic compound, and a fragrance. In one embodiment, the composition may comprise an alpha linoleic omega-3 fatty acid. The composition is suitably applied to breast adipose tissues to improve cosmetic appearance such as an increase in size or shape, and a decrease in sagging.

In combining these references, the Office states that it would have been obvious to one of ordinary skill in the art to modify the breast pad of Buckley et al. to provide the composition taught by Allen because the composition of Allen promotes improvement of the skin. Applicants assert that such a combination is not proper, and that a careful reading of the Allen reference actually teaches away from use of their composition on a breast pad as discussed below.

As stated in M.P.E.P. §2143, in order for the Office to show a *prima facie* case of obviousness, the Office must meet three criteria: (1) the prior art reference(s) must teach or suggest all of the claim limitations; (2) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; and (3) there must be some reasonable expectation of success. Applicants assert that the Office has not, and cannot, meet the burdens of either number (1) or number (2) above, which requires

KCC 4775 (K-C 17,129)
PATENT

the Office to show each and every claim limitation and some motivation to combine the cited references. The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. Applicants assert that the references, if combined do not contain all of the limitations of instant claim 1, nor is there motivation or suggestion to combine the references. Additionally, the Allen reference would actually have taught one skilled in the art away from its combination with Buckley et al.

In considering the scope and content of a prior art reference, "[the] prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention."⁶ Specifically, one skilled in the art and considering the Allen reference would have realized that the compositions of Allen are not suitable for use on a breast pad because of serious health concerns to both the mother, and the nursing infant. As such, the Allen reference fails to disclose and actually teaches away from the claimed limitation of a composition suitable for ingestion by a suckling infant.

As mentioned in Applicants' specification, the omega-3 fatty acid comprising composition introduced onto the breast pad will, to some extent, be ingested by the suckling infant as the composition is transferred from the breast pad to the breast and nipple skin to facilitate repair of skin. Moreover, the instant invention provides a dual benefit in that it helps to maintain

⁶W.L. Gore & Associates, Inc. v. Garlock, Inc., 721 F.2d 1540 (Fed. Cir. 1983) (The court noted that in considering prior art references, the reader cannot "disregard disclosures in the references that diverge from and teach away from the invention at hand.") See also M.P.E.P. §2141.02.

KCC 4775 (K-C 17,129)
PATENT

the breast and nipple skin of the mother and can also provide a dietary benefit to the suckling baby if ingested during breast feeding. The composition of Allen is strictly for topical application, as mentioned throughout their disclosure, and is not designed for ingestion. There is no mention that the composition of Allen is suitable for ingestion by an infant. Furthermore, as set forth in Example 1, Table A, the Allen composition may comprise sodium borate which, if ingested by an infant, can result in vomiting, diarrhea, shock and even death.

Additionally, the compositions of Allen comprise a natural estrogen compound. The introduction of an estrogen or estrogen producing compound into the tissue of a lactating mother can be dangerous to the health of the mother, and to the suckling infant. A close reading of the Allen reference by one skilled in the art leads to the inevitable conclusion that many of the chemical components suitable for use in the Allen composition for topical application are not suitable for ingestion by a suckling infant, which will happen if the composition is introduced onto a breast pad and transferred to the breast of the mother. When considering the Allen reference as a whole, as required by the M.P.E.P., one skilled in the art would recognize that such a composition was not designed for use on a breast pad where the composition could ultimately be ingested by a nursing infant.

In addition to the composition of Allen not being suitable for ingestion by the suckling infant, one skilled in the art would not have been motivated to combine Allen with the Buckley et al. reference as Allen does not teach or suggest a composition for treating the surface of the nipple and skin. As discussed in Applicants' specification, the omega-3 fatty acid-containing composition is introduced onto the breast pad such that it

KCC 4775 (K-C 17,129)
PATENT

contacts the surface of the breast and nipple skin during use so that it can help repair skin damage on the skin surface (stratum corneum) induced by suckling by providing lipids lost from the skin surface. As disclosed throughout the instant specification, specific examples of skin damage⁷ caused by breast feeding include breast and nipple infection, nipple cracking and peeling, and nipple fissures and ulcers, all which are considered damage to the surface of the breast and nipple skin. In direct contrast, the composition of Allen is specifically designed to penetrate epithelial barriers and stimulate changes in fatty acid metabolism in subcutaneous adipose tissues; that is, the Allen composition is designed to penetrate through the stratum corneum (the lipid-containing layer of skin), through the epidermis, through the dermis, and into the underlying adipose tissue where it can stimulate changes in fatty acid metabolism. Instead of working on the surface of the skin like the composition of claim 1, the Allen composition is specifically designed to penetrate many layers of skin deep into the adipose tissue. To this end, the Allen composition comprises a penetrant, or penetration enhancing agent, effective to increase the penetration of the emulsion into the subcutaneous tissues. This is in direct contrast to an application of a composition for skin repair on the surface of the skin as the composition set forth in claim 1 seeks to do.

Because the compositions of Allen comprise a penetrant and are designed to penetrate numerous layers of skin (and therefore are not designed or intended to treat the outer layer of the skin, i.e., the stratum corneum), the compositions of Allen are not suitable for use on a breast pad to improve skin and nipple

⁷Instant specification on page 4, lines 10-12.

KCC 4775 (K-C 17,129)
PATENT

health during breast feeding. The Allen compositions simply penetrate through the outer layers and deep into the skin and thus would not be of value on the stratum corneum. One skilled in the art and reading Allen would not, and could not, have been motivated to utilize the composition on a breast pad for treating the skin by replacing lipids on the outer layer of the skin as the Allen composition is designed to penetrate deeply into the subcutaneous layers. As such, motivation to combine these references would have been lacking.

Based on the foregoing, the combination of references by the Office is improper as there is no motivation or suggestion to make the combination by one skilled in the art. Additionally, such a combination fails to disclose each and every element of claim 1 as there is no composition disclosed that can improve breast and nipple skin health and is suitable for ingestion by an infant. As such, claim 1 is patentable.

Claims 1-16 depend from claim 1 and are patentable for the same reasons as claim 1, as well as for the additional elements they require.

Claim 17 is similar to claim 1 with the additional requirement that the composition further comprise omega-6 fatty acids. Claim 17 is patentable for the same reasons as claim 1, as well as for the additional elements it requires.

Claims 18-34 depend from claim 17 and are patentable for the same reasons as claim 17, as well as for the additional elements they require.

Claim 35 is similar to claim 1 with the additional requirement that the composition comprise essential fatty acids. Claim 35 is patentable for the same reasons as claim 1, as well as for the additional elements it requires.

KCC 4775 (K-C 17,129)
PATENT

Claims 36-52 depend from claim 35 and are patentable for the same reasons as claim 35, as well as for the additional elements they require.

Claim 53 is similar to claim 1 and requires that the composition comprise flaxseed oil. Claim 53 is patentable for the same reasons as claim 1, as well as for the additional elements it requires.

Claims 54 and 55 depend from claim 53 and are patentable for the same reasons as claim 53, as well as for the additional elements they require.

Claim 56 is similar to claim 1 wherein the composition comprises linoleic acid, alpha linoleic acid, eicosapentenoic acid, and docosahexenoic acid. Claim 56 is patentable for the same reasons as claim 1, as well as for the additional elements it requires.

Claim 57 depends from claim 56 and is patentable for the same reason as claim 56, as well as for the additional elements it requires.

Claim 58 is directed to a method of treating or preventing nipple tenderness and cracking comprising introducing a composition, suitable for ingestion by a suckling infant, comprising omega-3 fatty acids onto a breast pad and transferring the composition from the breast pad to the breast of the wearer. Claim 58 is similar to claim 1 and is patentable for the same reasons as claim 1, as well as for the additional elements it requires.

Claims 59-64 depend from claim 58 and are patentable for the same reasons as claim 58, as well as for the additional elements they require.

Claim 65 is similar to claim 58 and is patentable for the

KCC 4775 (K-C 17,129)
PATENT

same reasons as claim 58, as well as for the additional elements it requires.

Claims 66-71 depend from claim 65 and are patentable for the same reasons as claim 65, as well as for the additional elements they require.

Response to Arguments

In Examiner's Response to Arguments section, Examiner claims that Applicants are relying on features (i.e., a composition that can be safely ingested by a suckling infant) that are not recited in the rejected claims. As stated above, the "suitable for ingestion" feature is recited in the claim and there is support for the feature in the original specification. As further stated above, a composition suitable for ingestion must be appropriate or proper for ingestion by the infant.

Furthermore, even if this feature is not recited in the claim, one skilled in the art reading the application as a whole, which, as stated above, he would be required to do, would not be motivated to combine the Buckley et al. and Allen references because the composition of the Allen reference could kill the infant. This relates to the second prong the Examiner must show in making an obviousness rejection under 35 U.S.C. 103(a), that of requiring some suggestion or motivation to combine the references. This prong is distinct from the first prong requiring each and every element to be shown in the prior art references.

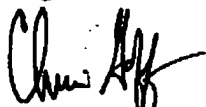
Additionally, the Examiner notes that the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art.

KCC 4775 (K-C 17,129)
PATENT

Specifically, the Examiner finds that the intended use of ingestion of the composition by the infant to improve the health of the infant does not distinguish the instant application because "all compositions are suitable for ingestion". As noted above in the dictionary definition of suitable, all compositions are not suitable for ingestion, as a suitable composition to be ingested must be appropriate or proper for ingestion by a baby. As stated above, a composition such as the composition taught in Allen is not suitable as it could kill the infant if ingested.

In view of the above, Applicants respectfully request favorable reconsideration and allowance of all pending claims. The Commissioner is hereby authorized to charge any fee deficiency in connection with this Letter To Patent And Trademark Office to Deposit Account Number 19-1345 in the name of Senniger, Powers, Leavitt & Roedel.

Respectfully Submitted,



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